REMARKS

Status

Claims 16-20, 22-24, and 27-36 are pending. Claims 20 and 27 are independent. Support for new Claims 27-36 is found at page 7, line 7 and in previously presented Claims 16-20 and 22-24. Accordingly, no new matter is incorporated by this Amendment.

It is noted that the rejection based on 35 U.S.C. § 112 in the previous Office Action, Paper No. 14, has been withdrawn in the presently outstanding Office Action. Applicants request clarification as to the disposition of the other rejections in Paper No. 14.

Rejection under 35 U.S.C. § 102

Claims 16, 17, 20 and 22 are rejected under 35 U.S.C. § 102(e) as being anticipated by Paul et al., U.S. Patent No. 6,241,983.

Applicants respectfully traverse.

Applicants claim a method for the inhibition or treatment of **systemic infections** in humans or vertebrates comprising administering, to humans or vertebrates **having a systemic infection** caused by pathogenic bacteria, a composition comprising an effective amount of a fermentable dietary fiber or a mixture of fermentable dietary fibers, wherein the composition is administered orally or through tube feeding. The Office Action in citing Paul et al. as anticipatory does not adequately address all the elements of the claimed invention; therefore it cannot anticipate. In sum, Paul et al. fails to teach, expressly or inherently, an element involving a systemic infection.

There is a critical distinction between a systemic infection, and the local or gastro-intestinal infection disclosed in Paul et al. Pathogenic bacteria may affect a subject in a number of ways, but the claimed invention is directed to a method involving a SYSTEMIC infection. By way of contrast, an infection localized in the gastro-intestinal tract caused by the presence of pathogenic bacteria in the stomach or in the intestine is properly characterized as LOCAL. On the other hand, infections

caused by bacteria inside the mucosal or epidermal wall or inside the body, such as, for example, in the blood or in the lymph, affect the body generally and are conventionally defined as SYSTEMIC.

An analysis of Applicants' specification bears out this distinction. In the examples in the specification, the animal models are injected intraperitoneally with an infective dose of pathogenic bacteria. Thus the infections in these animal models are systemic. In contrast, Paul et al. contains no disclosure that can be reasonably interpreted as disclosing an infection that is systemic. Paul et al. refers only to gastrointestinal pathogens (col. 3, ll. 44-46), or to a composition for maintaining gastrointestinal health (col. 16, ll. 21-25). In fact, the content of the stomach or intestine is conventionally considered to be outside the body, thus further distinguishing this disclosure from the claimed invention. In summary, Paul et al. merely teaches that a local (intestinal) infection is treated with the local application, by oral administration. Paul does not address treatment of a systemic infection in any way. Accordingly, there is no express disclosure in Paul et al. to anticipate the claimed invention.

Although the Office Action does not clearly state whether it is alleged that the disclosure in Paul et al. inherently anticipates the claimed invention, an analysis of Paul et al. contravenes this interpretation as in any way viable to support an anticipatory inherent disclosure. An inherent disclosure can only be adequate if it necessarily flows from the teaching in the reference. No mere probability of inherency will suffice. In Paul et al., there is no teaching that an infection is systemic or that pathogenic bacteria are present in the blood or lymph of a subject for treatment. In fact, there is not even a hint that the gastro-intestinal mucosal layer is ruptured in such a way that might allow bacterial translocation. Accordingly, there is no basis for an inherent disclosure that would anticipate the claimed invention.

For all the reasons above, Applicants respectfully request that the anticipatory rejection based on Paul et al. be withdrawn.

Rejection under 35 U.S.C. § 103

Claims 16-20 and 22-24 are rejected under 35 U.S.C. § 103(a) as rendered unpatentable based on the combination of Paul et al. with Van Loo et al., U.S. Patent No. 6,500,805.

Applicants respectfully traverse.

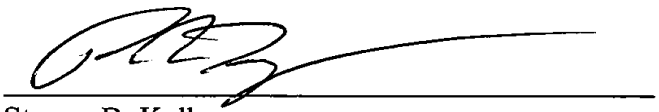
As indicated above, Paul et al. fails to address an element involving a systemic infection. Van Loo et al. fails to cure this deficiency. Accordingly, the obviousness rejection fails to address, *prima facie*, all the claim elements. Reconsideration and withdrawal are respectfully requested.

CONCLUSION

In light of the above, Applicants submit that this application is now in condition for allowance and therefore request favorable consideration. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephonic interview, the Examiner is respectfully requested to contact the undersigned at the telephone number listed below.

Respectfully submitted,

PIPER RUDNICK LLP



Steven B. Kelber
Registration No. 30,073
Attorney of Record

Patrick R. Delaney
Registration No. 45,338

1200 Nineteenth Street, N.W.
Washington, D.C. 20036-2412
Telephone No. (202) 861-3900
Facsimile No. (202) 223-2085